



FEB 22 2005

K043572

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**Premarket Notification 510(k) Summary**  
**As required by section 807.92**  
**Compatibility ECG Trunk Cables**

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

**COMPANY NAME/ADDRESS/PHONE/FAX:**

Datex-Ohmeda  
86 Pilgrim Road  
Needham, MA 02492 USA  
Tel: 781-449-8685  
Fax: 781-433-1344

**NAME OF CONTACT:**

Mr. Joel Kent

**DATE:**

December 23, 2004

**DEVICE NAME as required by 807.92(a)(2)**

**TRADE NAME:**

**Compatibility ECG Trunk Cables**

M1020453, 3-lead, from Multi-Link connector to 300 Series Leadset, IEC, 3.0 m/ 10 ft  
M1020454, 3-lead, from Multi-Link connector to 300 Series Leadset, AHA, 3.0 m/ 10 ft  
M1020541, 5-lead, from Multi-Link connector to 300 Series Leadset, IEC, 3.0 m/ 10 ft  
M1020546, 5-lead, from Multi-Link connector to 300 Series Leadset, AHA, 3.0 m/ 10 ft  
M1020547, 3/5-lead Trunk Cable from Round Nicolay Connector to Multi-Link Leadsets (3 or 5),  
IEC, 3.0 m/ 10 ft  
M1020563, 3/5-lead Trunk Cable from Round Nicolay Connector to Multi-Link Leadsets (3 or 5),  
AHA, 3.0 m/ 10 ft

**COMMON NAME:**

ECG Trunk Cables

**CLASSIFICATION NAME:**

The following Class II classifications appear applicable:

DSA     Cable, transducer and electrode, Patient including connector     870.2900

NAME OF LEGALLY MARKETING DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Compatibility ECG Trunk Cables (REF M1020453, M1020454, M1020541, M1020546, M1020547 and M1020563) are substantially equivalent in safety and effectiveness to the predicate Multilink ECG Cables (K980582).

DEVICE DESCRIPTION as required by 807.92(a)(4)

Compatibility ECG Trunk Cables are used during ECG measurement. These ECG trunk cables consist of connectors on each cable end and a shielded main electrical cable. Some products also have defibrillation protection resistors inside the yoke-connector. ECG trunk cables are used to transfer the ECG signal from lead sets to a patient monitor. These ECG trunk cables have limited skin contact with a patient while ECG leadwires attached on patient chest have more continuous skin contact.

Some products are used with legacy GE Medical System monitors like Dash 3000/4000, Solar, TRAM and also with the new S/5 modules like M-PRESTN. Before the patient monitor can display ECG signals on the screen, leadwire sets and electrodes are needed in addition to these trunk cables. With these trunk cables, 300-series Datex-Ohmeda ECG lead sets are needed.

Other products are used with legacy Datex-Ohmeda patient monitors and modules like Cardiocap 5, Light, or M-ESTPR having a blue and round 10-pin ECG connector. With these trunk cables, Multi-Link leadwire sets are used.

Products are packed individually into a plastic bag in non-sterile condition. Package label describes product REF codes, manufacturing date, CE-mark, legal entity information and a caution "Federal (USA) law restricts this device to sale by or on the order of a physician".

INTENDED USE as required by 807.92(a)(5)

Intended use:

The intended use for these trunk cables is to transmit an ECG signal from different GE Healthcare ECG leadwire sets to GE Healthcare patient monitors.

Indication for use:

Compatibility ECG Trunk Cables with green monitor side plug are used to connect Datex-Ohmeda 300-series leadwire sets to GE Healthcare patient monitors having green and rectangle GEEC-type 11-pin ECG connector. Compatibility ECG Trunk Cables with blue monitor side plug are used to connect GE Multi-Link leadwire sets to legacy Datex-Ohmeda patient monitors having a blue and round Nicolay-type ECG connector.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Compatibility ECG Trunk Cables (REF M1020453, M1020454, M1020541, M1020546, M1020547 and M1020563) are substantially equivalent in safety and effectiveness to the predicate Multilink ECG Cables (K980582).

The Compatibility ECG Trunk Cable has the following similarities to the predicate device:

- Non sterile, reusable ECG Trunk cable
- Same monitor side connector on four products and same yoke connector on two products
- Same type cable materials

The proposed Compatibility ECG Trunk Cable has the following differences compared to the Multi-Link predicate device:

- Cable length
- Instruction for use
- Availability of 12-leadwire trunk cable

In summary, Compatibility ECG Trunk Cables, described in this submission are substantially equivalent to the predicate Multilink cables (K980582).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Compatibility ECG Trunk Cables have been assessed against the standards below.  
The device has been thoroughly tested through validation and verification of specifications.

- EN 60601-1:1990 +A1:1993 +A2:1995 +A13:
- 21 CFR Part 898
- EN 980:2003
- EN 1041:1998
- ISO 10993-5:1995, ISO 10993-10:1996
- ANSI/AAMI EC53-1995
- ANSI/AAMI EC13-2002 Paragraphs:- 4.2.2.2.1, 4.2.2.2.3 ,4.2.6.1 ,4.2.9.3 ,4.2.9.4 ,4.2.9.14
- ISO 14971:2000

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Compatibility ECG Trunk Cables as compared to the predicate device.



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

FEB 22 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Datex-Ohmeda  
c/o Mr. Joel Kent  
Manager, Quality and Regulatory Affairs  
86 Pilgrim Road  
Needham, MA 02492

Re: K043572

Trade Name: Compatability ECG Trunk Cables

M1020453, Compatibility Trunk Cable, 3-lead, from Multi-Link connector to 300 Series Leadset, IEC, 3.0 m/10 ft

M1020454, Compatibility Trunk Cable, 3-lead, from Multi-Link connector to 300 Series Leadset, AHA, 3.0 m/10 ft

M1020541, Compatibility Trunk Cable, 5-lead, from Multi-Link connector to 300 Series Leadset, IEC, 3.0 m/10 ft

M1020546, Compatibility Trunk Cable, 5-lead, from Multi-Link connector to 300 Series Leadset, AHA, 3.0 m/10 ft

M1020547, Compatibility Multi-Link 3/5 lead Trunk Cable, from Round Nicolay connector to Multi-Leadsets (3 or 5), IEC, 3.0 m/10 ft

M1020563, Compatibility Multi-Link 3/5 lead Trunk Cable, from Round Nicolay connector to Multi-Leadsets (3 or 5), AHA, 3.0 m/10 ft.

Regulation Number: 21 CFR 870.2900

Regulation Name: Patient Transducer and Electrode Cable (including connector)

Regulatory Class: II (two)

Product Code: DSA

Dated: December 23, 2004

Received: December 27, 2004

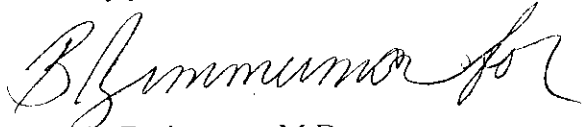
Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours, 

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K043572

Device Name: Compatibility ECG Trunk Cables

### Indications for Use:

Compatibility ECG Trunk Cables with green monitor side plug are used to connect Datex-Ohmeda 300-series leadwire sets to GE Healthcare patient monitors having green and rectangle GEEC-type 11-pin ECG connector. Compatibility ECG Trunk Cables with blue monitor side plug are used to connect GE Multi-Link leadwire sets to legacy Datex-Ohmeda patient monitors having a blue and round Nicolay-type ECG connector

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

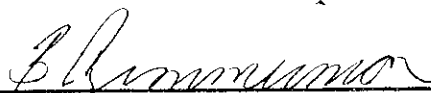
AND/OR

Over-The-Counter Use         
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K043572